# Serological Science for COVID-19


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*Frederick National Laboratory Advisory Committee*

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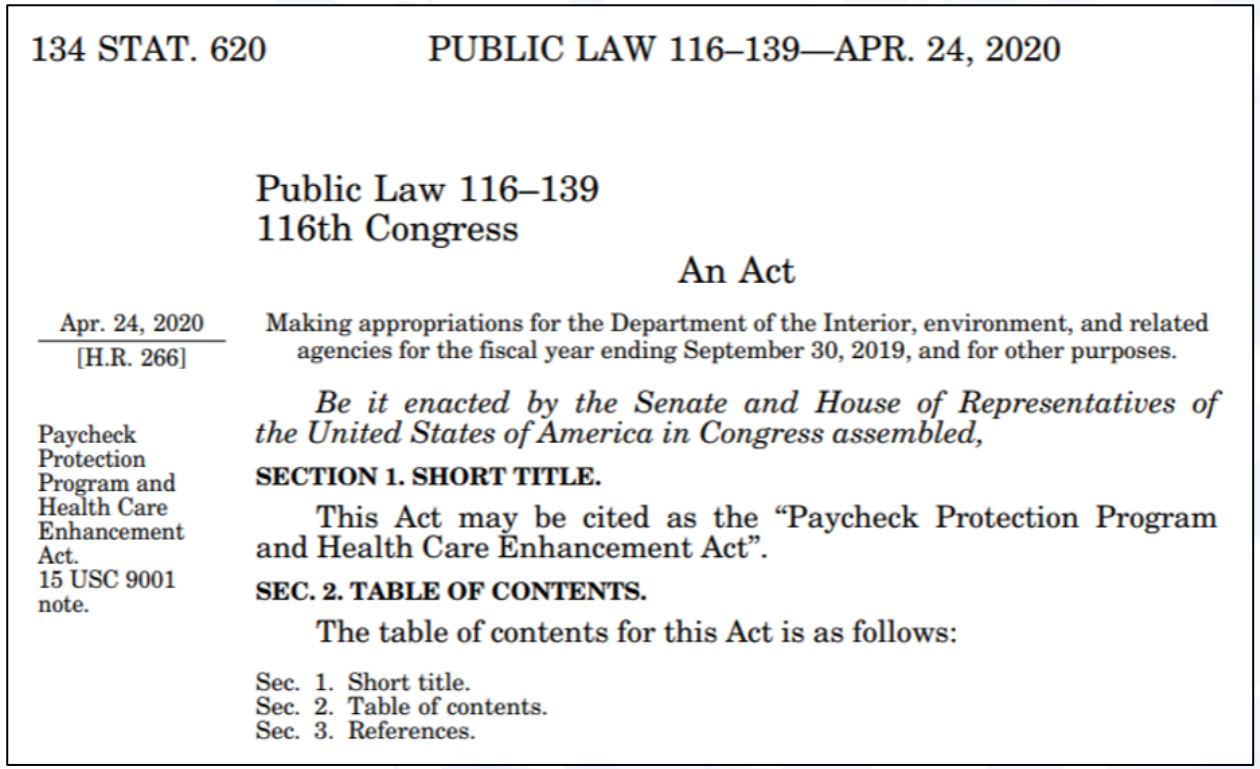
NIH NATIONAL CANCER INSTITUTE

# Supplemental funding from Congress

- Enacted April 24th
- $306M for NCI to **develop**, **validate**, **improve**, and **implement** serological testing and associated technologies
- COVID-19 focused and *distinct* from annual appropriation



134 STAT. 620 PUBLIC LAW 116–139—APR. 24, 2020

Public Law 116–139
116th Congress

An Act

Apr. 24, 2020
[H.R. 266]

Making appropriations for the Department of the Interior, environment, and related agencies for the fiscal year ending September 30, 2019, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

Paycheck Protection Program and Health Care Enhancement Act.
15 USC 9001 note.

**SECTION 1. SHORT TITLE.**

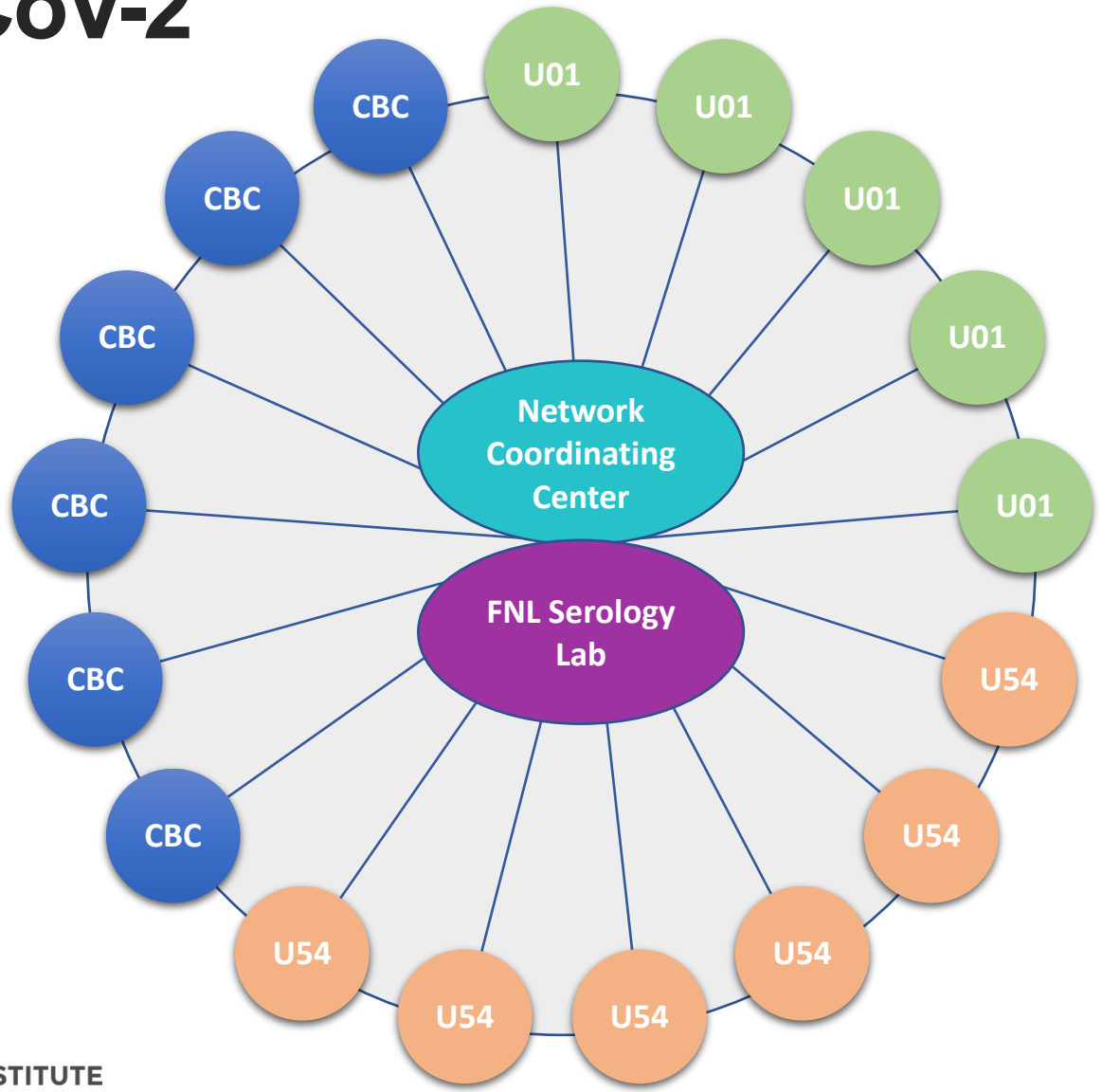
This Act may be cited as the "Paycheck Protection Program and Health Care Enhancement Act".

**SEC. 2. TABLE OF CONTENTS.**

The table of contents for this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. References.

# Proposed Serological Sciences Network for SARS-CoV-2




**4-8 CBCs**: Serological Sciences Capacity Building Centers (RFP)

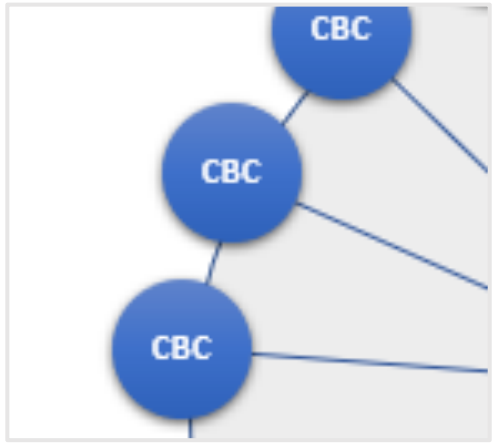
**4-8 U54s**: Serological Sciences Centers of Excellence (RFA)

**5-10 U01s**: Serological sciences projects (RFA)


# FNLCR Serology Lab

- Implement and validate SARS-CoV-2 Serology assays for different viral antigens and different isotypes (IgM, IgG, IgA)
- Build validation and proficiency panels for assay development and validation
  - Rapidly identify, procure, and characterize serum/plasma specimens from SARS-CoV-2 patients and necessary controls to identify negative, low, medium and high responses
- Produce assay standards and reference reagents (antigens) for qualification/validation of SARS-CoV-2 serological and other relevant immune assays and distribute to the network
- Implement standardized testing capability to support vaccine trials and cancer research
- Evaluation of determinants of neutralizing responses
- Partnership with regulatory bodies and assay developers for validation of serology testing platforms

# Serological Sciences Capacity Building Centers




## RFP

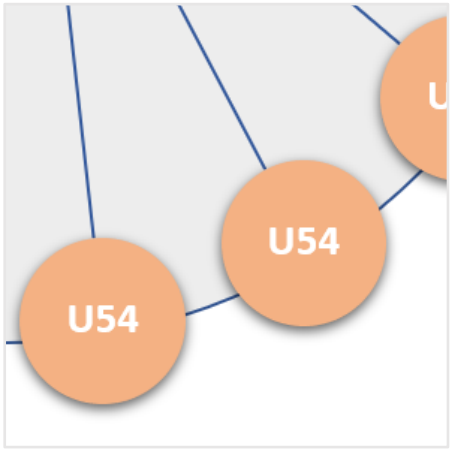
**4-8 contracts** with academic and/or private sector through FNLCR

**Up to $3M** total costs per year, per site

## Goals

- Develop and expand serological testing capacity and practice in the community
  - Implementation of serological standardization, assay development and availability of FDA-EUA authorized SARS-CoV-2 testing to identify those who may have been exposed to the virus.
  - Scale up acquired serological testing to provide increased national capacity by screening at least 10,000 patients per week with FDA-EUA authorized assays
- Acquire convalescent sera from recovered COVID-19 patients who are seropositive and conduct surveillance clinical trials in patients who have recovered from COVID-19 and are seropositive
- Pursue focused serological science

# Serological Sciences Centers of Excellence (RFA)




**4-8 U54 awards**

**Up to $2M** total costs per year for up to 5 years

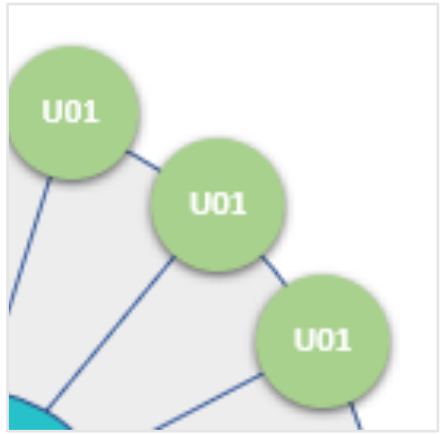
## Goals

- Understand the mechanisms driving the serological, humoral and cellular immune responses to SARS-CoV-2 viral infection to inform the development of novel serological tests
- Determine the serological correlates with disease pathogenesis and protection against future infection
- Improve population-based models of outbreak and susceptibility through serology-focused studies
- Preference for cancer relevant component

Each Center will have 2-3 projects, administrative core and the possibility of technical core

*Budget set-aside for collaborative projects proposed post-award*

# Serological sciences projects (RFA)




**5-10 U01 awards**

**Up to $500K** direct costs per year, up to 5 years

## Goals

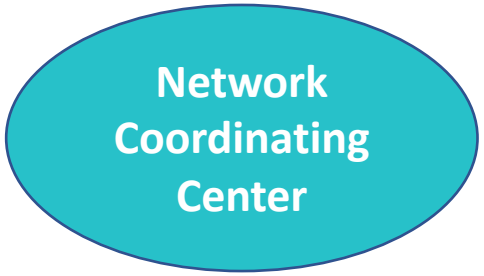
- Understand the mechanisms driving the serological, humoral and cellular immune responses to SARS-CoV-2 viral infection to inform the development of novel serological tests
- Determine the serological correlates with disease pathogenesis and protection against future infection
- Improve population-based models of outbreak and susceptibility through serology-focused studies
- Preference for cancer relevant component

*Budget set-aside for collaborative projects proposed post-award*

# **Notice of Intent to Publish a Funding Opportunity:** Serological Sciences Centers of Excellence (NOT-CA-20-066)

- Estimated RFA publication date: June 10, 2020
- Estimated due date: July 20, 2020
- Estimated award date: September 30, 2020
- Applications will be reviewed by a Special Emphasis Panel convened by NCI

# Network Coordinating Center at Frederick National Lab




**FNLCR Task Order**

**$750K total costs per year**

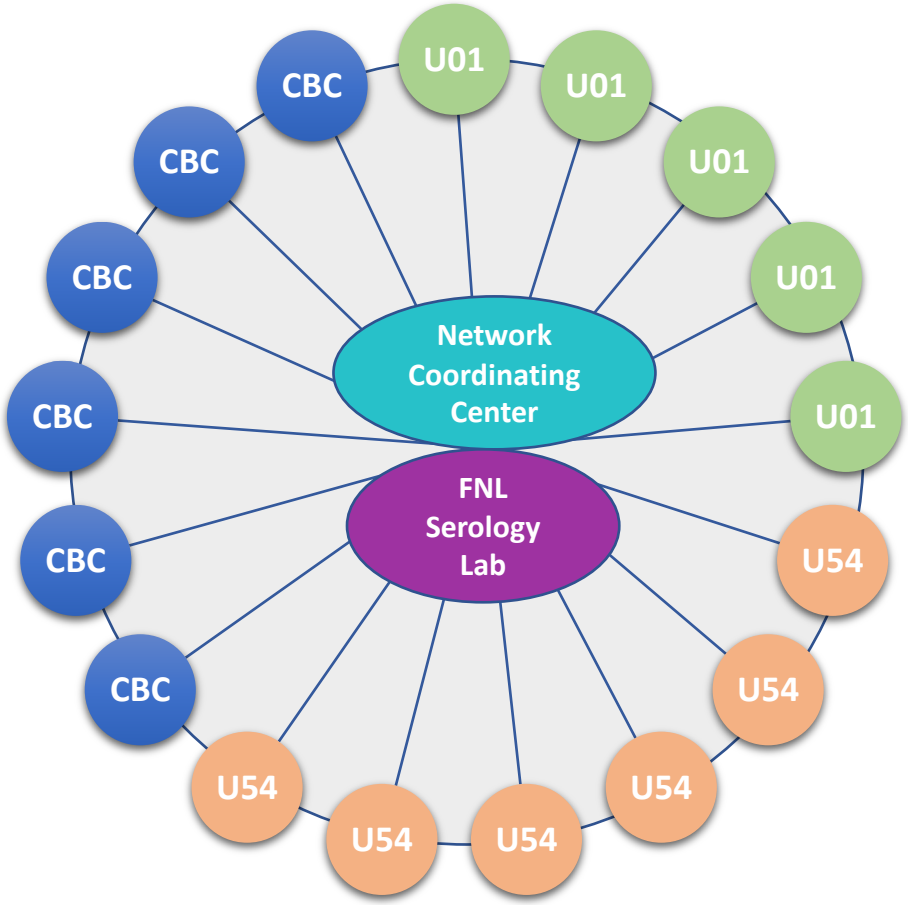
## Goals

- Provide program management, coordination and communication across the Serological Sciences Network for SARS-CoV-2
- Coordinate sharing of the data, reagent, sample, and assays
- Coordinate comparison of results among different centers and assays through inter-Center collaborative studies, leading to international serology standardization
- Coordinate partnerships with national and international associates such as the FDA, CDC, WHO, National Institute for Biological Standards and Control (NIBSC), and others
- Work in close collaboration with NCI program staff

# **Request for Information:**
# Strategy for Research in Coronavirus Serology Testing and Serological Sciences (NOT-CA-20-065)

- Seeking input from the research community on scope of Serological Sciences Network
- RFI will be open to response until May 26, 2020
- Responses will be reviewed and incorporated into the design of the technological and scientific scope of the Network

# The Serological Sciences Network




## *With Special Thanks to:*

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